CLAIMS

We claim:

1. An extended release dosage form comprising:

a tablet core comprising at least one drug and a water soluble polymer in the form of a matrix, the tablet core being surrounded by an outer surface, and

an enteric coating completely covering the outer surface of the tablet core, the coating comprising an enteric polymer and a pore-former distributed within the enteric polymer.

2. The dosage form of claim 1, wherein the enteric coating reduces any burst effect that would be exhibited by the tablet core in the absence of the enteric coating.

3. The dosage form of claim 1, wherein the drug is less soluble in an aqueous solution at a pH of greater than about pH 5.0 than it is at a pH of below about pH 5.0.

4. The dosage form of claim 3, wherein the drug is an antibiotic.

5. The dosage form of claim 4, wherein the antibiotic is clindamycin.

6. The dosage form of claim 5, wherein the clindamycin is in the form of crystalline clindamycin free base.

7. The dosage form of claim 1, wherein the water soluble polymer is selected from the group consisting of: a cellulose ether, hydroxypropylcellulose, sodium carboxymethyl cellulose, xanthan gum, acacia, tragacanth gum, guar gum, karaya gum, alginates, gelatin, albumin.

8. The dosage form of claim 1, wherein the water soluble polymer is hydroxypropylmethyl cellulose.

9. The dosage form of claim 1, wherein the tablet core further comprises at least one binder.

10. The dosage form of claim 9, wherein the at least one binder is microcrystalline cellulose and magnesium stearate.

11. The dosage form of claim 1, wherein the enteric polymer is selected from the group consisting of: a methacrylic acid/methacrylic acid ester copolymer, a methacrylic acid/acrylic acid ester copolymer, cellulose acetate phthalate, hydroxypropyl

methylcellulose pthalate, hydroxypropyl methyl cellulose acetate succinate, cellulose acetate trimellitate, and polyvinyl acetate phthalate.

12. The dosage form of claim 1, wherein the enteric polymer is a polyvinyl acetate phthalate.

13. The dosage form of claim 1, wherein the pore-former is a water soluble polymer.

14. The dosage form of claim 13, wherein the water soluble polymer pore-former is hydroxypropylmethyl cellulose.

15. A pH independent extended release dosage form comprising:

a tablet core matrix, comprising a crystalline clindamycin free base and a water soluble polymer in the form of a matrix, the tablet core having an outer surface, and

an enteric coating covering the entire outer surface of the tablet core, comprising an enteric polymer and a pore-former distributed within the enteric polymer.

16. The dosage form of claim 15, wherein the water soluble polymer is selected from the group consisting of: a cellulose ether, hydroxypropylcellulose, sodium carboxymethyl cellulose, xanthan gum, acacia, tragacanth gum, guar gum, karaya gum, alginates, gelatin, albumin.

17. The dosage form of claim 15, wherein the water soluble polymer is hydroxypropylmethyl cellulose.

18. The dosage form of claim 15, wherein the tablet core further comprises at least one binder.

19. The dosage form of claim 18, wherein the at least one binder is microcrystalline cellulose and magnesium stearate.

20. The dosage form of claim 15, wherein the enteric polymer is selected from the group consisting of: a methacrylic acid/methacrylic acid ester copolymer, a methacrylic acid/acrylic acid ester copolymer, cellulose acetate phthalate, hydroxypropyl methylcellulose pthalate, hydroxypropyl methyl cellulose acetate succinate, cellulose acetate trimellitate, and polyvinyl acetate phthalate.

21. The dosage form of claim 15, wherein the enteric polymer is polyvinyl acetate phthalate.

22. A method of treating or preventing a gram positive bacterial infection in a subject, comprising: orally administering to the subject a tablet of the dosage form of claim 15, wherein the tablet core comprises a pharmaceutically effective amount of the crystalline clindamycin free base.

23. The method of claim 22, wherein the subject is a mammal.

24. The method of claim 22, wherein the subject is a human.

25. The method of claim 22, wherein the amount of the crystalline clindamycin free base in the tablet core is 500-2000 mg.

26. A method of making a drug release dosage form, comprising the steps of:

a. dry mixing intragranular ingredients comprising a drug, hydroxypropylmethyl cellulose, microcrystalline cellulose, and magnesium stearate, thereby producing an intragranular mixture;

b. processing the intragranular mixture through a roller compactor;

c. dry mixing extragranular ingredients, comprising hydroxypropylmethyl cellulose, microcrystalline cellulose, and magnesium stearate with the intragranular ingredients, thereby producing a core tablet mixture;

d. pressing the core tablet mixture in a tablet press to produce a tablet core;

e. coating the tablet core with an enteric coat comprising an enteric polymer and a pore former.

27. The method of claim 26, wherein at least one of the intragranular ingredients is provided in a sized form for dry mixing in step (a).

28. The method of claim 26, wherein all intragranular ingredients except the magnesium stearate are dry mixed in a first mixing step, producing an intermediate intragranular mixture, followed by dry mixing the intermediate intragranular mixture with the magnesium stearate.

29. The method of claim 26, wherein all extragranular ingredients are initially mixed together with the intragranular ingredients mixture from step (a) except for magnesium

stearate, and magnesium stearate is subsequently mixed therewith.

30. The method of claim 26, wherein the drug is an antibiotic.

31. The method of claim 30, wherein the drug is crystalline clindamycin free base.